

REMARKS

By the present amendment, claim 1 has been amended to replace the listing of items (f)-(j) by a listing (a)-(d) (optional clause (j) is deleted from claim 1), claim 2 has been amended to replace “polymer” by “polymers” and “a mixture thereof” by “mixtures thereof,” claim 8 has been amended to insert a space between “claim” and “1,” and claims 12-14 have been amended to insert “a” before “different beneficial agent.”

Further, claim 1 has been amended to recite that the cover composition over the passageway does not completely cover the coat. Support for the added recitation is found in the original application, for example, it is immediately derived from the description of the Figures from page 4, line 30 to page 6, line 4 together with the description of the polymeric composition, for example, page 17, lines 10-16, page 18, lines 22-26, page 19, lines 33-35, page 33, lines 11-15, and its illustration in the form of band or plug.

Claim 3 has been amended to replace “susceptible to the gastric environment” by “susceptible to decreased stability in the gastric environment.” Support for the added recitation is found in the original application, for example, on page 18, lines 10-21.

New claims 19-22 dependent directly or indirectly on claim 1 and reciting a cover composition forming at least one of a plug or band blocking the passageway and covering only the orifice, respectively, have been added.

New claim 23 dependent on claim 1 and reciting the feature of deleted optional clause (j) of original claim 1 has been added.

Claims 1-23 are pending in the present application. Claim 1 is the only independent claim.

I. Objections

In the Office Action, the specification is objected to as containing typographical errors, i.e., page 3, line 5 (“being to referred to” should be “being referred to”) and page 3, line 32 (an extra space between “agents is” should be deleted).

Also, in the Office Action, claims 1, 2, 8, and 12-14 are objected to as follows:

- Claim 1: items (f)-(j) should be listed as (a)-(e);
- Claim 2: “a” should be inserted before “water soluble polymer,” “water swellable polymer,” and “pH-dependent polymer”;
- Claim 8: a space should be inserted between “claim” and “1”;
- Claims 12-14: “a” should be inserted before “different beneficial agent.”

The specification and claims 1, 2, 8, and 12-14 have been amended as suggested in the Office Action, except that, in claim 1, optional clause (j) has been deleted (new dependent claim 23 has been added for the corresponding recitation), and in claim 2, the Markush group has been amended to recite “polymers” and “mixtures thereof.” Accordingly, it is submitted that the objections should be withdrawn.

II. Double patenting rejections

In the Office Action, claims 1-5, 7-8, and 11-15 are provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 11-15 of co-pending U.S. Appl. No. 11/946,575.

Further, claims 1-5, 7-8, and 11-15 are provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 25, 32, 38, and 39-41 of co-pending U.S. Appl. No. 10/572,502.

It is acknowledged in the Office Action that the claims of the '575 and '502 applications do not recite a "passageway" but it is alleged that selective removal of the coating inherently functions as a passageway, and that the features of the dependent claims are either inherent or obvious.

Reconsideration and withdrawal of the rejections is respectfully requested. It is submitted that the '575 and '502 claims do not teach or suggest the features of the presently claimed invention, for example, a passageway in the coat and a composition applied so as to cover the passageway, wherein said cover composition does not completely cover the coat, as recited in clauses (c) and (d) of present claim 1.

In view of the above, it is submitted that the rejections should be withdrawn.

III. Indefiniteness rejection

In the Office Action, claims 3 and 5 are rejected under 35 U.S.C. 112, second paragraph, as indefinite. It is alleged in the Office Action that the term "susceptible" in claim 3 is unclear without a qualifying action, and that the expression "cause bleeding or irritation" in claim 5 is contradictory with the term "beneficial agent."

Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 3 has been amended to replace "susceptible to the gastric environment" by "susceptible to decreased stability in the gastric environment."

Regarding claim 5, the objection is respectfully traversed. It is submitted that some beneficial agents, along with giving a beneficial effect, may also give some side effects such as causing bleeding or irritation to the gastric mucosa. Reference is made to the specification at page 14, lines 28-31, which provides examples of such compounds (aspirin, steroids, non-steroid anti-inflammatory compounds). Thus, it is submitted that the recitation in claim 5 is clear and definite to a person of ordinary skill in the art.

In view of the above, it is submitted that the rejection should be withdrawn.

IV. Art rejections

In the Office Action, claims 1-11 and 16-18 are rejected under 35 U.S.C. 102(b) as anticipated by US 6,491,949 to Faour et al. ("Faour").

Further, claims 12-15 are rejected under 35 U.S.C. 103(a) as obvious over Faour in view of US 5,229,131 to Amidon et al. ("Amidon").

Reconsideration and withdrawal of the rejections is respectfully requested. Faour only discloses a coated tablet having a passageway, with an immediate release composition as outside layer completely covering the tablet. In addition to the requirement for material to completely cover the tablet, other drawbacks of a full coating layer as taught by Faour include the fact that certain beneficial agents are likely to be destabilized by polymers forming the composition because of a chemical interaction in between them. For example, enteric polymers may destabilize beneficial agents such as proton pump inhibitors.

In contrast, in the presently claimed invention, the cover composition covering the passageway does not completely cover the coat, as recited in present claim 1. An advantage of

this feature is that it is possible to reduce physical contact or interaction with the polymer that can affect the stability of the active ingredient present in the core, while achieving a same effect of programmed delivery of the active ingredient.

In addition, with respect to the dependent claims, it is submitted that the combined features of each of these respective claims are not taught or suggested by the cited references. In particular, with respect to claims 19-22, Faour fails to teach or suggest a cover composition forming at least one of a plug or band blocking the passageway, or a cover composition covering only the orifice, and Amidon fails to remedy this deficiency. Therefore, each of the dependent claims, and in particular, each of claims 19-22, is not anticipated by Faour, and not obvious over Faour taken alone or in any combination with the other cited references.

In view of the above, it is submitted that the rejections should be withdrawn.

Conclusion

In conclusion, the invention as presently claimed is patentable. It is believed that the claims are in allowable condition and a notice to that effect is earnestly requested.

If there is, in the Examiner's opinion, any outstanding issue and such issue may be resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number listed below.

Application No. 10/551,456
Art Unit: 1615

Amendment under 37 CFR §1.111
Attorney Docket No.: 053180

If this paper is not considered to be timely filed, the Applicants hereby petition for an appropriate extension of the response period. Please charge the fee for such extension and any other fees which may be required to Deposit Account No. 50-2866.

Respectfully submitted,
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